Sklar
INSTRUMENTS
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West Chester, PA 19382
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APR - 9 2010

Exhibit 1

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: K091720.

1. **Submitter's Identification:**

   Sklar Instruments
   889 South Matlack Street
   West Chester, PA 19382
   Tel: 800-221-2166

   Date Summary Prepared: April 2, 2010

2. **Name of the Device:** SklarLite™ Rigid Sterilization Container System
   Class II, Product Code KCT

3. **Common or Usual Name:** Closed Sterilization Container

4. **Predicate Device Information :**
   Miltex Rigid Sterilization Container System, Miltex, Incorporated, K050570

5. **Device Description :**
   The SklarLite™ Rigid Sterilization Container System consists of a family of rigid, re-usable, stackable, sealed containers that provide an effective sterilization packaging method for medical devices. Container bottoms and lids, within a given size, are interchangeable. Containers can be fitted with safety lids, protecting filters during storage and/or transport. The system consists of the following components:

   - Container bottoms (both perforated and non-perforated versions)
   - Container lids (both perforated and non-perforated versions)
   - Container baskets
   - Container labels
   - Disposable filters

   The container system is designed for sterilant penetration through perforations in the lid and container bottom models that are perforated. Containers are offered in six colors. Filter media and sterilization indicator cards should be used in conjunction with the containers. Containers are protected by disposable plastic security seals.

6. Intended Use:

The SklarLite™ Rigid Sterilization Container System is intended for use in hospitals and health care facilities to contain other medical devices that are to be sterilized. Containers allow sterilization of the enclosed medical devices, including surfaces and lumens, using high vacuum steam sterilizers at 270°F for 4 minutes with 30 minutes (minimum) dry time.

The containers have been validated for sterilization of up to two instruments with lumens no smaller than 2.4 mm I.D. in diameter and no longer than 380 mm in length for the Full-Size (580mm x 280mm) and Mid-Size (465mm x 280mm) containers, and no smaller than 1.0 mm I.D. in diameter and no longer than 250 mm in length for the Half-Size (285mm x 280mm) container. Containers have been validated for a combined maximum load of 25lbs. with up to two internal stacked baskets and up to two silicon mats (one mat per basket) for the Full-Size, Mid-Size and Half-Size containers. Both solid and perforated bottom containers, maximum depth 150mm/each, can be stacked a maximum of 3 containers high during sterilization.

Sterilized devices may be stored and transported within the container. The container is intended to maintain sterility of the contents for up to six (6) months.

8. Technological Characteristics as Compared to the Predicate Device:

	Sklar System	**Miltex System**
PROPERTIES		
Indicated for use containing instruments to be sterilized in vacuum steam sterilizers	Yes	Yes
Intended to be re-used	Yes	Yes
Closed System	Yes	Yes
Sealed	Yes	Yes
DESIGN		
Incorporates a filter system to permit entry of sterilant agents	Yes	Yes
Incorporates a filter system to prevent microbial migration during transport	Yes	Yes
MATERIALS:		
Container	Anodized Aluminum Alloy, stainless steel & silicon	Aluminum alloy, stainless steel & silicon
Color	Silver, yellow, red, blue, green and black	Silver

9. Performance Data as Compared to the Predicate Device:

	Sklar System	Miltex System
PERFORMANCE DATA		
Conformance to appropriate AAMI standards	Conforms to AAMI/ANSI ST77:2006 standard	Conforms to AAMI/ANSI ST77 Draft

VALIDATION TESTING		
Pre-vacuum steam	Yes	Yes
Load	Up to 25 lbs. for all container sizes.	Up to 16 lbs. (small) Up to 20 lbs. (med.) Up to 25 lbs. (large)
TEST ORGANISMS		
Inoculated Lumens	(2) 2.4mm I.D. x 380mm, metal for ~~Full and Mid Size~~ container models. (2) 1.0mm I.D. x 250mm, metal for Half-Size container models.	3mm I.D. x 400mm, metal (large ~~containers) and 3mm~~ I.D. x 200mm, metal (medium and small containers)
Inoculated Stainless Steel Medical Devices	Yes	Yes

10. Conclusions:

The studies conducted on the SklarLite™ Rigid Sterilization Container System demonstrate that the device is substantially equivalent to the Miltex Rigid Sterilization Containers (K050570).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Sklar Corporation
C/O Ms. Natalya Valerio
Official Correspondent
MDI Consultants, Incorporated
55 Northern Boulevard, Suite 200
Great Neck, New York 11021

APR - 9 2010

Re: K091720
Trade/Device Name: SklarLite™ Rigid Sterilization Container System
Regulation Number: 21CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: KCT
Dated: April 2, 2010
Received: April 5, 2010

Dear Ms. Valerio:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K091720

Device Name: SklarLite™ Rigid Sterilization Container System

Indications For Use:

The SklarLite™ Rigid Sterilization Container System is intended for use in hospitals and health care facilities to contain other medical devices that are to be sterilized. Containers allow sterilization of the enclosed medical devices, including surfaces and lumens, using high vacuum steam sterilizers at 270°F for 4 minutes with 30 minutes (minimum) dry time.

The containers have been validated for sterilization of up to two instruments with lumens no smaller than 2.4 mm I.D. in diameter and no longer than 380 mm in length for the Full-Size (580mm x 280mm) and Mid-Size (465mm x 280mm) containers, and no smaller than 1.0 mm I.D. in diameter and no longer than 250 mm in length for the Half-Size (285mm x 280mm) container. Containers have been validated for a combined maximum load of 25lbs. with up to two internal stacked baskets and up to two silicon mats (one mat per basket) for the Full-Size, Mid-Size and Half-Size containers. Both solid and perforated bottom containers, maximum depth 150mm/each, can be stacked a maximum of 3 containers high during sterilization.

Sterilized devices may be stored and transported within the container. The container is intended to maintain sterility of the contents for up to six (6) months.

Prescription Use _____ (Per 21 CFR 801 Subpart D)

OR

Over-The Counter Use X (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K091720

Indications for Use

The sterilization containers which are the subject of this premarket notification are as follows:

SklarLite™ Rigid Sterilization Containers* with Filter System
**All Container Models are offered in the following colors: Silver, Yellow, Red, Blue, Green and Black.*

MODEL	Perforations	Dimensions	Load Limit
Full Size Containers Basic/Safe Models	Perforated Lid and Non Perforated Bottom	580 x 280 x 100	25 lbs.
		580 x 280 x 135	25 lbs
		580 x 280 x 150	25 lbs
		580 x 280 x 200	25 lbs
		580 x 280 x 260	25 lbs
	Perforated Lid and Perforated Bottom	580 x 280 x 100	25 lbs
		580 x 280 x 135	25 lbs
		580 x 280 x 150	25 lbs
		580 x 280 x 200	25 lbs
		580 x 280 x 260	25 lbs
Mid Size Containers Basic/Safe Models	Perforated Lid and Non Perforated Bottom	465 x 280 x 100	25 lbs
		465 x 280 x 135	25 lbs
		465 x 280 x 150	25 lbs
	Perforated Lid and Perforated Bottom	465 x 280 x 100	25 lbs
		465 x 280 x 135	25 lbs
		465 x 280 x 150	25 lbs
Half Size Containers Basic /Safe Models	Perforated Lid and Non Perforated Bottom	285 x 280 x 100	25 lbs
		285 x 280 x 135	25 lbs
		285 x 280 x 150	25 lbs
		285 x 280 x 200	25 lbs
		285 x 280 x 260	25 lbs
	Perforated Lid and Perforated Bottom	285 x 280 x 100	25 lbs
		285 x 280 x 135	25 lbs
		285 x 280 x 150	25 lbs
		285 x 280 x 200	25 lbs
		285 x 280 x 260	25 lbs
		600 x 400 x 180	25 lbs